DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

#9

Re: RIMADYL
Docket No.: 97E-0012

SEP 29 1998

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,264,500, filed by PFIZER INC., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for RIMADYL, the animal drug product claimed by the patent.

The total length of the regulatory review period for RIMADYL is 6,572 days. Of this time, 5,910 days occurred during the testing phase and 662 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 512(j) of the Federal Food, Drug, and Cosmetic Act involving this animal drug product became effective: October 30, 1978.

   The applicant claims August 23, 1979, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's letter assigning a number to the INAD was October 30, 1978, which is considered to be the effective date for the INAD.

2. The date the application was initially submitted with respect to the animal drug product under subsection (b) of the Federal Food, Drug, and Cosmetic Act: January 3, 1995.

   The applicant claims December 29, 1994, as the date the New Animal Drug Application (NADA) for RIMADYL (NADA 141-053) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to NADA 141-053 was January 3, 1995, which is considered to be the initially submitted date for NADA 141-053.

3. The date the application was approved: October 25, 1996.

FDA has verified the applicant's claim that NADA 141-053 was approved on October 25, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: J. Trevor Lumb
Pfizer Inc.
Patent Department
235 East 42nd Street
New York, NY 10017-5755